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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,973	12/14/2005	Francois Perraut	034299-674	9588

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EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,973	PERRAUT ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 12 is objected to because of the following informalities:

Claim 12 recites in lines 3-4, "subtracting the sum of all of the pixels of the first zone (25) from the sum of all the pixels of the second zone". The claim appears to be reciting that the sum of all the pixels, *i.e., the number of pixels*, of the first zone is subtracted from the sum of all the pixels, i.e., the number of pixels, of the second zone. However, Applicants' specification shows that this is really not the case, but rather the *signals* from the sum of the pixels in the first zone of interest is subtracted from that in the second zone of interest (see specification on page 7, lines 18-24 and page 13, lines 20- 28).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ault-Riche et al., US 2004/0241748, in view of Woudenberg et al., 6,660,147.

As to claim 8, Ault-Riche et al. teach a method of providing capture agents which bind to binding partners for diagnostic tests (paragraph [0015] and [0016] and [0442]) and utilizing an imaging device such as an optical scanner device that generates digital image data output as TIFF files (paragraph [0443]). The processing is controlled by a computer, and each array is printed and prepared for processing, which exposes the array to reagents for observing reactions or interactions of interest, and each array is then inserted into an array handling apparatus chamber that positions each array in its desired location of imaging ([0442]). Thus, Ault-Riche et al. teach placing a sample in a chamber, as well as the claimed step of defining one or more regions of interest so that measuring information can be extracted.

The step of utilizing an imaging device such as an optical scanner device that generates digital image data or color images is deemed to be Applicants' claimed step of producing an image including the image of the beam diffused by the sample. Generating TIFF files is deemed to be recording the spatial structure of the image [i.e., as TIFF files],

Ault-Riche et al. teach that assessment of an effect includes a chemical change, or a change in kinetics of the reaction, among other things (paragraph [0030]). Ault-Riche et al. also teach that the invention includes providing self-assembled arrays with capture agents, the array or collection of arrays having loci that are subjected to reagent materials or other processing for observation of chemical or biological reactions

(paragraph [0437]). Ault-Riche et al. further teach that the image data is useful for depicting an optical appearance or characteristic of each locus on the array or collection of arrays, such as indicating luminosity of the loci, or reflectivity of the loci under particular types of illuminating light and that the image data is useful for detecting a change in the optical appearance or characteristic of each locus after biological processing, such as chemical or biological reaction ([0438]). Thus, Ault-Riche et al. teach illuminating a sample using a light beam coming from a source. The step of detecting the image is considered to be Applicants' claimed step of extracting information specific to the light/sample beam interaction. The step of detecting a *change* in the optical appearance or characteristic of each locus after biological processing such as a chemical or biological reaction is deemed to the claimed step of examining the spatial structure of the image and distribution of light energy in the image with respect to one or more references (i.e., the appearance or characteristic of each locus *before* biological processing). This disclosure also show that there is extracting and recording of measuring information (i.e., the optical appearance or characteristic).

Ault-Riche disclose detecting the presence of the analyte (see paragraph 0501) using fluorescent labels (see paragraph 160) and also quantitating them (see paragraph 0542), either of which is deemed to be the step of calculating of the assay with respect to the measuring information. Ault-Riche et al. also teach that the TIFF image data can be received directly from the imaging device or over a device communication interface, and the user provides array processing input selections for the image data that is to be processed and analyzed ([0443]).

Ault-Riche et al. teach placing a sample in a chamber ([0442]), but do not teach that the chamber has transparent sides. (Ault-Riche et al. is silent as to transparency of the chamber.)

However, Woudenberg et al. teach an assay device wherein the channel array is preferably optically transparent or at least includes transparent regions or windows which permit viewing of part or all of each channel, and optionally permit viewing of the chambers, passageways, and/or other elements of the channel array (col. 7, lines 32-37.) Silica-based glasses, quartz, polycarbonate, or an optically transparent plastic layer may be used for example (col. 7, lines 37-39). Woudenberg et al. disclose that selection of the particular transparent material will depend in part on the optical properties of the material and the spectroscopic characteristics of the signal to be detected, and that for example, in a fluorescence-based assay, the material should have low fluorescence emission at the wavelength(s) being measured, and the window material should also exhibit minimal light absorption for the signal wavelengths of interest (col. 7, lines 39-46.) Woudenberg et al. teach that in one embodiment, sample components or target analytes are measured by fluorescence detection, and that the detection zone of each channel can be illuminated by a suitable light source, and the sample components signals can be collected by one or more channels simultaneously using an area-type detector including various imaging instruments.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the Ault-Riche et al. chamber from a transparent material because Woudenberg et al. teach that a transparent material provides the benefit of

being able to view an assay as well as to detect target analytes by, for example fluorescence detection, and collect the detection signals by using imaging instruments. The skilled artisan would have reasonable expectation of success in fluorescence detection using transparent material throughout a chamber (which would include the sides) because the Ault-Riche et al. invention also relies on fluorescence detection (see paragraph 160).

As to claim 9, the diffusion is particle scattering (paragraph [0438]; and paragraph [0288] for example). (The image generated is considered to be an image including the particle scattering of the particles in the sample.)

As to claim 10, the assay is calculated with respect to a calibration between the light energy measurement and the sample amount (paragraph [00542]).

As to claim 11, the assay is calculated with respect to the analysis of the kinetics of the biological or chemical reaction (paragraph [0030]).

As to claim 12, Applicants claim that a first zone of interest around the illuminated volume zone, which corresponds to the volume of the chamber excited by the light beam, and a second zone of interest next to this first zone are defined, and that the measuring information is obtained by subtracting the sum of all the pixels of the first region of interest from the sum of all the pixels of the second region of interest. This is disclosed by Ault-Riche et al. because Ault-Riche et al. teach an image correction processing that involves compensating for locus neighbor effects in the locus image data. Ault-Riche et al. teach that the neighbor effects compensation involves examining luminosity data for all the array loci adjacent to each locus of interest. The technique

removes luminosity effects from sources other than the locus of interest and therefore can contribute to more accurate luminosity data for the array loci over the surface of the array or collection of array (see paragraph [0446] and [0449]. Any one of the locus adjacent the locus of interest is deemed to be Applicants' first region of interest and the locus of interest is deemed to be Applicants' claimed second region of interest. The removal of the luminosity for all the array loci adjacent to the locus of interest from the luminosity of the locus of interest is deemed to be Applicants' step of subtracting the sum of all the pixels of the first region of interest from the sum of all the pixels of the second region of interest. It is noted that Ault-Riche et al. teach use of a CCD camera or optical scanner device that generates digital image or color images (paragraph [0438]) and that the image data from the array(s) is processed on a pixel by pixel basis (paragraph [0448]). Removal of the luminosity for all the array loci, or just one loci, adjacent to the locus of interest from the luminosity of the locus of interest thus results in the subtraction of the sum of the luminosity detected by the pixels detecting the first region of interest from the sum of the luminosity detected by the pixels detecting the second region of interest.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ault-Riche et al., US 2004/0241748, in view of Massey et al., 6,362,011.

Ault-Riche et al. disclose the invention substantially as claims (see above regarding claim 8.) However, Ault-Riche does not disclose *deriving* the concentration of fluorescent molecules contained in a solution. Ault-Riche disclose detecting the presence of the analyte (see paragraph 0501) using fluorescent labels (see paragraph 160) and also quantitating them (see paragraph 0542). However, Ault-Riche et al. do not disclose the specific steps in quantitating the fluorescent probes. More specifically Ault-Riche et al. do not teach that the quantitating step includes *deriving* the *concentration* of fluorescent molecules.

Massey et al. however disclose that in detection of an analyte, a label can be induced to luminesce and the luminescence emitted can be used to detect the presence of the analyte and that those same methods may be used to quantify the amount of analyte in a sample by comparing the luminescence of a composition containing a known amount of analyte (col. 2, lines 53 – col. 3, line 7.) Such comparison to determine concentration is deemed to be deriving the concentration (i.e., deriving a known amount of composition per volume by a comparison with a known sample). Massey also disclose that fluorescence is a type of luminescence (col. 1, lines 42-48.)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to quantify analytes, as taught by Massey et al., in the Ault-Riche et al. method (wherein the luminescent labels are fluorescent—paragraph 160 and 0542)

because Massey et al. teach that quantification of an analyte can be performed using the same method of detection and comparing the detection with the luminescence of a composition containing a known amount of analyte. One of ordinary skill in the diagnostic art would recognize the desirability of not just detecting the presence of an analyte, but also quantifying the amount of analyte in a sample, as disclosed by Massey et al.

Response to Arguments

Applicants' arguments filed December 29, 2006 have been fully considered but they are not persuasive.

As to the 112, second paragraph regarding the original claim 6, Applicants argue that new claim 12, which corresponds with canceled claim 6, makes clear that the measuring information is obtained by subtracting the sum of all of the pixels of the first region of interest from the sum of all of the pixels of the second region of interest, and that the language of this claim is supported in the specification at page 6, lines 28 – page 7, line 2. However, Applicants' cited passage only reads "--lighting the sample by means of a light beam from a source, characterised in that it also comprises the following steps: --producing an image including the image of the light diffused by the sample," (it is noted that Applicants should change the spelling using "s" to –z— where appropriate in the application.) However, this cited passage does not support "subtracting the sum of all of the pixels of the first zone (25) from the sum of all the

pixels of the second zone" as recited in claim 12, lines 3-4. It understood that Applicants intend to mean that the *signals* from the sum of the pixels in the first zone of interest is subtracted from that in the second zone of interest (see specification on page 7, lines 18-24 and page 13, lines 20- 28), rather than the sum of all the pixels, which would mean *the number of pixels*, of the first zone being subtracted from the sum of all the pixels, i.e., the number of pixels, of the second zone. However, the language should be corrected to clarify the claim.

As to the 112, second paragraph rejection of original claim 7, which has been canceled and replaced by new claim 13, this 112, second paragraph rejection is hereby withdrawn due to the amendment.

As to the substance of the claims, Applicants assert that new claim 8 includes the following elements:

recording the spatial structure of the image;

examining the spatial structure of the image and distribution of light energy in the image with respect to one or more references, and defining one or more regions of interest so that measuring information can be extracted;

extracting the measuring information;

recording the measuring information; and

calculating the assay with respect to the measuring information.

Applicants also assert that Ault-Riche does not disclose or suggest the foregoing elements. However, because Examiner finds that Ault-Riche does teach those elements (see rejection of claim 8 above) and because Applicants do not give further

reasons as to why Applicants find that Ault-Riche does not disclose or suggest such elements, Applicants' argument is not persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

3/19/07

ANN YEN LAM
PATENT EXAMINER